Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1.-38. (cancelled)

- 39. (new) A composition for delivery of a drug comprising a condensation aerosol
- a) wherein the condensation aerosol is formed by heating a thin film of a drug composition to produce a vapor, and condensing the vapor to form a condensation aerosol comprising the drug.
- wherein the condensation aerosol comprises particles that are characterized by less than 10% drug degradation products by weight,
- wherein the condensation aerosol has an MMAD of less than 5 microns, and
 - d) wherein the drug is a heat stable respiratory drug.
- 40. (new) The composition of claim 39, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphylline, tofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant,

ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil.

- 41. (new) The composition of claim 39, wherein the condensation aerosol particles are characterized by less than 5% drug degradation products.
- 42. (new) The composition of claim 41, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitax sentan, tezosentan, iloprost, treprostinil.
- 43. (new) The composition of claim 39, wherein the condensation aerosol particles are characterized by less than 1% drug degradation products.
- 44. (new) The composition of claim 43, wherein the heat stable drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol,

Serial No.: 10/719,899

Attorney Docket No.: 00068.01R

tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphylline, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil.

- 45. (new) The composition of claim 39, wherein the drug composition comprises a drug that is in a free base form.
- 46. (new) The composition of claim 39, wherein the drug composition comprises a drug that is in a free acid form.
- (new) The composition of claim 39, wherein the drug composition comprises at least two drugs.
- (new) The composition of claim 39, wherein the drug composition comprises a pharmaceutically acceptable excipient.
- (new) The composition of claim 39, wherein the condensation aerosol is devoid of excipients.
- 50. (new) The composition of claim 39, wherein the condensation aerosol is devoid of propellants and organic solvents.
- 51. (new) The composition of claim 39, wherein the condensation aerosol particles are characterized by increasing percentages of drug degradation products with increasing film thicknesses.

52. (new) The composition of claim 51, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitax sentan, tezosentan, iloprost, treprostinil.

- 53. (new) The composition of claim 39, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
- 54. (new) The composition of claim 53, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone,

hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil.

- 55. (new) The composition of claim 39, wherein the condensation aerosol is characterized by an MMAD of 1 to 5 microns.
- 56. (new) The composition of claim 55, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitax sentan, tezosentan, iloprost, treprostinil.
- 57. (new) The composition of claim 39, wherein the condensation aerosol is characterized by an MMAD of 10 to 100 nm.
- 58. (new) The composition of claim 57, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol,

fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphylline, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil.

- 59. (new) The composition of claim 39, wherein the condensation aerosol is characterized by an MMAD of 1 to 3 microns.
- 60. (new) The composition of claim 59, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitax sentan, tezosentan, iloprost, treprostinil.

61. (new) The composition of claim 59, wherein the condensation aerosol particles are characterized by less than 5% drug degradation products.

- 62. (new) The composition of claim 61, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitax sentan, tezosentan, iloprost, treprostinil.
- 63. (new) The composition of claim 61, wherein the condensation aerosol particles are characterized by less than 1% drug degradation products.
- 64. (new) The composition of claim 63, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium

bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil.

- 65. (new) The composition of claim 39, wherein the thin film has a thickness between 0.05 and 20 microns.
- 66. (new) The composition of claim 65, wherein the thin film has a thickness between 0.5 and 5 microns.
- 67. (new) A kit for delivering a condensation aerosol, the kit comprising:
- a) a thin film of a drug composition comprising a drug, on a solid support,
 and
 - a device for providing the condensation aerosol,

wherein the condensation aerosol is formed by heating the drug composition to produce a vapor, and condensing the vapor to form a condensation aerosol comprising the drug,

wherein the condensation aerosol comprises particles that are characterized by less than 10% drug degradation products by weight,

wherein the condensation aerosol has an MMAD of less than 5 microns, and wherein the drug is a heat stable respiratory drug.

- 68. (new) The kit of claim 67, wherein the thin film has a thickness between 0.05 and 20 microns.
- 69. (new) The kit of claim 67, wherein the thin film has a thickness between 0.5 and 5 microns.

70. (new) The kit of claim 67, wherein the device comprises a heating element configured to heat the thin film to produce a vapor, and an enclosure allowing the vapor to condense to form a condensation aerosol.

- 71. (new) The kit of claim 67, wherein the condensation aerosol comprises more than one drug.
- 72. (new) The kit of claim 67, wherein the drug composition further comprises a pharmaceutically acceptable excipient.
- 73. (new) The kit of claim 67, wherein the heat stable respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitax sentan, tezosentan, iloprost, treprostinil.
- 74. (new) The kit of claim 67, wherein the condensation aerosol has an MMAD of less than 3 microns
- 75. (new) The kit of claim 67, wherein the condensation aerosol has an MMAD of 1 to 5 microns.

76. (new) The kit of claim 67, wherein the condensation aerosol has an MMAD of 10 to 100 nm.

- 77. (new) The kit of claim 67, wherein the condensation aerosol has an MMAD of 1 to 3 microns.
- 78. (new) The kit of claim 67, wherein the solid support is a metal foil.
- 79. (new) The kit of claim 67, wherein the condensation aerosol particles are characterized by less than 5% drug degradation products.
- 80. (new) The kit of claim 67, wherein the condensation aerosol particles are characterized by less than 1% drug degradation products.